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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

IN RE: BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	MDL No. 1699
RICHARD MCNABB, and ALBERT SMITH Plaintiffs, v. PFIZER, INC., PHARMACIA CORPORATION, G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), and MONSANTO COMPANY, Defendants.	Case No. _____ **CIVIL COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs, Richard McNabb, and Albert Smith by and through their counsel, bring this action against Defendants PFIZER, INC., PHARMACIA CORP., MONSANTO COMPANY, and G.D. SEARLE LLC. (hereinafter collectively "Defendants") and allege as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medication

Valdecoxib, trade name BEXTRA® ("BEXTRA").

2. Plaintiff Richard McNabb was at all relevant times adult resident citizens of the State of Florida, County of Pinellas. Richard McNabb was prescribed and began taking BEXTRA for the treatment of pain. As a direct and proximate result of using BEXTRA, Plaintiff suffered severe injuries while taking BEXTRA, including, but not limited to, a stroke on or about December 23, 2004, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death. .

3. Plaintiff Albert Smith was at all relevant times adult resident citizens of the State of South Carolina, County of Aiken. Albert Smith was prescribed and began taking BEXTRA for the treatment of pain. As a direct and proximate result of using BEXTRA, Plaintiff suffered severe cardiovascular injuries while taking BEXTRA, including, but not limited to, a heart attack on or about December 21, 2004, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

4. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly $60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA in California and nationwide.

5. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling BEXTRA nationwide and in California. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

6. Defendant Monsanto Company ("Monsanto") was the parent corporation of Searle and is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product BEXTRA nationwide.

7. Defendant Pharmacia Corporation ("Pharmacia ") is a Delaware corporation with

its principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling BEXTRA nationwide and in California.

II. JURISDICTION AND VENUE

8. This is an action for damages, which exceeds seventy-five thousand dollars ($75,000.00).

9. There is complete diversity of citizenship between the Plaintiffs and Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000.00, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

10. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in the district, thereby receiving substantial financial benefit and profits the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

11. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, BEXTRA. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold Nationwide the aforementioned prescription drug. Defendants do substantial business in the State of California and within this Federal Judicial District, advertise in this district, receive substantial compensation and profits from sales of BEXTRA in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the agent for each of the other defendants, or those defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

12. Assignment to the San Francisco Division is proper as this action is related to *In Re: BEXTRA and CELEBREX Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,

2005. (See also, MDL-1699 Pretrial Order No. 2)

IV. FACTUAL BACKGROUND

A. Facts Regarding All Plaintiffs

13. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries unaware - and could not have reasonably known or have learned through reasonable diligence - that such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from Plaintiffs' ingestion of BEXTRA.

14. Plaintiffs used BEXTRA in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

15. Plaintiffs would not have used BEXTRA had Defendants properly disclosed the risks associated with the drug.

B. Facts Regarding Bextra's Market Launch

18. BEXTRA is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

19. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

20. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

21. Prostaglandin I2 is the predominant cyclooxygenase product in endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2

and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2 is a potent platelet aggregator and vasoconstrictor, which is synthesized by platelets. Therefore, while the older NSAIDS suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

22. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

23. Defendants and other pharmaceutical companies set out to remedy these ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing inflammation.

24. In making this decision, Defendants and their predecessors in interest either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels and causes thromboxane A_2 to be uninhibited, causing blood clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke and unstable angina.

25. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of their new "blockbuster" drug over less inexpensive NSAIDs. In May 1999, Merck & Co., Inc. ("Merck") launched Vioxx, its own selective COX-2 inhibitor.

26. Seeking increased market share in this extremely lucrative market, Defendants, and their predecessors in interest, also sought approval of a "second generation" selective COX-2 inhibitor and filed for FDA approval of BEXTRA on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrheal, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

27. The FDA granted approval of the new drug on November 16, 2001, for two particular uses: (i) treatment of primary dysmenorrheal and (ii) relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

28. The FDA did not grant approval to market and promote BEXTRA for the management or prevention of acute pain.

29. The FDA did not grant approval to promote BEXTRA as more effective than other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers or gastric bleeding.

30. Even without a label that allowed Defendants to legitimately claim superior safety, when Defendants, and their predecessors-in-interest, began marketing BEXTRA in early 2002, Defendants and their representatives and agents misrepresented the safety profile of BEXTRA to consumers, including Plaintiffs, the medical community, healthcare providers, and third party payers. Defendants proceeded to promote, market, sell, and distribute BEXTRA as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

C. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.

31. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in November 2, 2001. By 1997, and prior to the submission of the New Drug Application (the "NDA") for BEXTRA, Defendants was aware that, by inhibiting COX-2, BEXTRA altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954. Although all COX-2 inhibitors have this mechanism of action, BEXTRA was the most selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

32. Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it

was known as early as 1999 that selective COX-2 inhibitors, such as BEXTRA, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

33. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the FDA for BEXTRA, omitting information about the extent of the risks associated with BEXTRA. Without a complete picture of the potential hazards associated with the drug, the FDA approved BEXTRA on or about November 16, 2001.

34. Based on the studies performed on Celebrex, Vioxx, BEXTRA, and other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when BEXTRA was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2 inhibitors, including BEXTRA, decrease blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

35. On December 9, 2004, the FDA issued new information on side effects associated with the use of BEXTRA and required the addition of certain warnings to, and the strengthening of other warnings on, the BEXTRA label. The enhanced warnings followed in the wake of the results of additional cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA regarding severe skin reactions.

36. Yet well prior to this warning, Defendants had knowledge of the coronary and cardiovascular safety risks of BEXTRA from several studies. *See e.g.*, Otto, E.O., *Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery*, *The Journal of Thoracic and Cardiovascular Surgery*, June 2003 at 1481.

37. Even Defendants' own (and Pfizer funded) post- drug approval meta-analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data showing

an increased cardiovascular risk in patients treated with BEXTRA after undergoing coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood clots in the legs and lungs. The results were particularly relevant and striking as each of the study participants who were a post-bypass surgery patient was taking anti-clotting agents at the time their exposure to BEXTRA was being tracked.

38. In mid-January 2005, a peer-reviewed paper from the University of Pennsylvania found that in patients having heart bypass surgery, those who took BEXTRA in the intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a heart attack or stroke.

39. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

40. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of BEXTRA, Defendants failed to take any action to protect the health and welfare of patients, but instead, continued to promote the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

41. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily withdraw" BEXTRA from the U.S. market, stating:

> ". . . the Agency has concluded that the overall risk versus benefit profile of BEXTRA is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that BEXTRA has not been shown to offer any unique advantage over the other available NSAIDs."

42. FDA Alert for Healthcare Professionals, April 7, 2005.

43. Continuing, the FDA noted:

> "BEXTRA has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery. . . . FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for BEXTRA from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding. . . . To date, there have been no studies that demonstrate an advantage of BEXTRA over other NSAIDs that might offset the concern about the [ ] serious skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products."

44. The scientific data available during and after BEXTRA's approval process made clear to Defendants that their formulation of BEXTRA would cause a higher risk of blood clots, stroke and/or myocardial infarctions among BEXTRA consumers, alerting them to the need to do additional and adequate safety studies.

45. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing to humans ". . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

46. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

47. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of BEXTRA did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take BEXTRA. Therefore, Defendants' testing and studies were grossly inadequate. *See, e.g.*, PDR entry for BEXTRA.

48. Had Defendants done adequate testing prior to approval and "market launch," rather than the extremely short duration studies done on the small size patient base that was actually done, Pharmacia and Searle's scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects for individuals such as Plaintiffs. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

49. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

50. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

51. At the time Defendants manufactured, advertised, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as Plaintiffs would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAIDs.

D. Facts Regarding Defendants' Marketing and Sale of Bextra

52. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive BEXTRA as a safer and better drug than its other NSAIDs and, therefore, purchase BEXTRA.

53. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

54. Despite knowledge of the dangers presented by BEXTRA, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

55. In an elaborate and sophisticated manner, Defendants aggressively marketed BEXTRA directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include BEXTRA on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add BEXTRA to their formularies. Defendants' marketing campaign specifically targeted third

party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of BEXTRA.

56. Defendants represented that BEXTRA was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants promoted BEXTRA as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

57. BEXTRA possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, BEXTRA was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

58. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved BEXTRA for sale on November 16, 2001, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of BEXTRA. Defendants' omission, suppression, and concealment of this important information enabled BEXTRA to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

59. Consequently, BEXTRA captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002), sales of BEXTRA exceeded $1.5 billion, despite the significantly higher cost of BEXTRA as compared to other pain relievers in the same family of drugs.

60. It was not until April 7, 2005, that Defendants finally acknowledged BEXTRA's deleterious side effects and announced that they were withdrawing the drug from the worldwide

market based on what it misleadingly termed "new" and "unexpected" evidence linking BEXTRA to an increased risk of heart attacks and strokes.

61. Had Defendants done adequate testing prior to approval and "market launch," Pharmacia's scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

62. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but this information was intentionally suppressed by Defendants in order for them to gain significant profits from continued BEXTRA sales.

63. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

64. At the time Defendants manufactured, advertising, and distributed BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

65. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers, including Plaintiffs, and their doctors would perceive BEXTRA as a better drug than its competitors and, therefore, purchase BEXTRA.

66. Defendants widely and successfully marketed BEXTRA throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.

Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

67. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers, including Plaintiffs, were unreasonably subject to risk of injury or death from the consumption of Defendants' product, BEXTRA.

68. Despite such knowledge, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiffs, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

69. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

70. Defendants owed Plaintiffs a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

71. At all relevant times to this action, Defendants owed a duty to properly warn

Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug BEXTRA.

72. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of BEXTRA, including: failing to use due care in the preparation and development of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

a. failing to use due care in the design of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

b. failing to conduct adequate pre-clinical testing and research to determine the safety of BEXTRA;

c. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of BEXTRA;

d. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the medical community, and the FDA;

e. failing to accompany BEXTRA with proper warnings regarding all possible adverse side effects associated with the use of BEXTRA;

f. failing to use due care in the manufacture, inspection, and labeling of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;

g. failing to use due care in the promotion of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

h. failing to use due care in the sale and marketing of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

i. failing to use due care in the selling of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. failing to provide adequate and accurate training and information to the sales representatives who sold BEXTRA;

k. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of BEXTRA; and

l. being otherwise reckless, careless and/or negligent.

73. Despite the fact that Defendants knew or should have known that BEXTRA caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market BEXTRA to consumers, including Plaintiffs, when safer and more effective methods of pain relief were available.

74. Defendants were, or should have been, had they exercised reasonable care, in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of BEXTRA.

75. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

76. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

77. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

78. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF

Strict Liability

79. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

80. At all times relevant to this action, Defendants were suppliers of BEXTRA, placing the drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiffs without substantial change in the condition in which it was manufactured and sold.

81. BEXTRA was unsafe for normal or reasonably anticipated use.

82. BEXTRA was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. BEXTRA was also defective and unreasonably dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated with the design and/or formulation of the product.

83. BEXTRA is unreasonably dangerous: a) in construction or composition; b) in design; c) because an adequate warning about the product was not provided; d) because it does not conform to an express warranty of the manufacturer about the product.

84. The characteristics of BEXTRA that render it unreasonably dangerous existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

85. The BEXTRA manufactured and supplied by Defendants was also defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate testing before exposing Plaintiffs to the medication, testing which would have shown that BEXTRA had the potential to cause serious side effects including strokes like that which affected Plaintiffs.

86. The BEXTRA manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from BEXTRA, they failed to provide adequate warnings to the

medical community and the consumers, to whom they were directly marketing and advertising BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe and effective.

87. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective design of BEXTRA, Plaintiffs used BEXTRA rather than other safer and cheaper NSAIDs. As a result, Plaintiffs suffered the personal injuries described above.

88. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of BEXTRA, especially the information contained in the advertising and promotional materials, did not accurately reflect the potential side effects of BEXTRA.

89. Had adequate warnings and instructions been provided, Plaintiffs would not have taken BEXTRA as they did, and would not have been at risk of the harmful side effects described herein.

90. Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by BEXTRA.

91. Plaintiffs could not, through the exercise of reasonable care, have discovered BEXTRA's defects or perceived the dangers posed by the drug.

92. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

93. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to

punish Defendants and deter them from similar conduct in the future.

94. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF

Breach of Express Warranty

95. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

96. Defendants expressly represented to Plaintiffs and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

97. These warranties came in the form of:

a. Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;

c. Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiffs' ingestion of BEXTRA, and;

e. advertisements.

98. The documents referred to above were created by and at the direction of Defendants.

99. Defendants knew or had reason to know that BEXTRA did not conform to these express representations in that BEXTRA is neither as safe nor as effective as represented, and that BEXTRA produces serious adverse side effects.

100. BEXTRA did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

101. Plaintiffs, other consumers, and the medical community relied upon Defendants' express warranties.

102. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

103. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

104. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF

Breach of Implied Warranty

105. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

106. Defendants manufactured, distributed, advertised, promoted, and sold BEXTRA.

107. At all relevant times, Defendants knew of the use for which BEXTRA was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

108. Defendants were aware that consumers, including Plaintiffs, would use BEXTRA for treatment of pain and inflammation and for other purposes.

109. Plaintiffs and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for BEXTRA.

110. BEXTRA reached consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

111. Defendants breached their implied warranty to consumers, including Plaintiffs; BEXTRA was not of merchantable quality or safe and fit for its intended use.

112. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

113. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

114. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages and punitive and exemplary damages together with interest, the costs of

suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF

Fraudulent Misrepresentation & Concealment

115. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

116. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of BEXTRA, and their intentional dissemination of promotional and marketing information about BEXTRA for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about BEXTRA's risks and harms to doctors and consumers.

117. Defendants made fraudulent affirmative misrepresentations with respect to BEXTRA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that BEXTRA had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that BEXTRA was safer than other alternative medications.

118. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of BEXTRA.

119. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that BEXTRA had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiffs.

120. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to, the

cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of BEXTRA in order to increase its sales.

121. The representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Plaintiffs, rely upon them.

122. Defendants' representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and encourage the sale of BEXTRA.

123. Defendants' fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

124. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of BEXTRA in selecting BEXTRA treatment.

125. Plaintiffs and the treating medical community did not know that the representations were false and were justified in relying upon Defendants' representations.

126. Had Plaintiffs been aware of the increased risk of side effects associated with BEXTRA and the relative efficacy of BEXTRA compared with other readily available medications, Plaintiffs would not have taken BEXTRA as he did.

127. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

128. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers,

including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

129. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF

Unjust Enrichment

130. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

131. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of BEXTRA.

132. Plaintiffs paid for BEXTRA for the purpose of managing their pain safely and effectively.

133. Defendants have accepted payment from Plaintiffs for the purchase of BEXTRA.

134. Plaintiffs did not receive the safe and effective pharmaceutical product for which she paid.

135. It is inequitable and unjust for Defendants to retain this money because Plaintiffs did not in fact receive the product Defendant represented BEXTRA to be.

136. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;

4. Restitution;

5. Punitive and exemplary damages;

6. Pre-judgment and post-judgment interest as provided by law;

7. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

8. Such other and further relief as the Court deems just and proper.

Dated: December 19, 2007

Respectfully submitted,

By: Navan Ward, Jr.

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ATTORNEYS FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: December 19, 2007 By: Navan Ward, Jr.

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